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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,274	10/31/2006	Jianyi Zhang	09531-144US1 Z03175	3474

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EXAMINER

KIM, TAEYOON

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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04/20/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/560,274	ZHANG, JIANYI	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/26/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-12) and annexin and myocardium as elected species in the reply filed on 1/11/2010 is acknowledged.

Claims 13-20 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-12 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for annexin V, does not reasonably provide enablement for any other annexin subfamily other than annexin V (or A5). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The current claims generically disclose any annexin can be used for the method of directing a cell to damaged or diseased tissue or organ.

It is construed that the property of annexin (especially annexin V) of binding necrotic cells and/or apoptotic cells is a critical feature of the claimed invention.

The specification discloses annexin V in Examples of targeting or directing cells tagged with annexin V to damaged or diseased tissue including myocardial tissue. However, the

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specification failed to provide enabling embodiment and/or working examples that any of known annexin, except annexin V, shown in Fig. 1 of Gerke et al. (2002).

The prior art including Narula et al. (2001, IDS ref.) and Vermes et al. (1995; IDS ref.) teaches that the binding of annexin to necrotic cells and/or apoptotic cells are mediated annexin V. However, there is no known other annexin used for the same purpose.

Therefore, it is highly unpredictable that other annexin family members other than annexin V can be used for the claimed method without undue experimentation.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for tissue or organ having necrotic and/or apoptotic cells, does not reasonably provide enablement for other damaged or diseased tissue or organ which does not contain any necrotic or apoptotic cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The currently claimed invention discloses the method of using a tagged cells with annexin, especially annexin V, to direct the cells to a damaged or diseased tissue or organ in an individual.

Since the scope of the limitation of “damaged” or “diseased” is extremely broad encompassing not only those comprising necrotic and/or apoptotic cells, but also those without necrotic and/or apoptotic cells. For example, the “damaged” or “diseased” tissue can be those with any tissue or organ which might have missing functions, mutations in genes, or any

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abnormalities leading loss of functions but not necessarily leading to necrosis and/or apoptosis of cells in the tissue or organ.

The claimed method is based on the property that the tagged cells would be directed to the target tissue or organ because of high affinity of the binding member, i.e. annexin V, to necrotic and/or apoptotic cells. Therefore, it is considered that the claimed invention is not enabling for those "damaged" or "diseased" tissue or organ without necrosis or apoptosis.

In short, the specification does not provide enablement for a person of ordinary skill in the art to make/use the claimed invention commensurate in scope with the instant claims without undue experimentations.

Conclusion

No claims are allowed. Claims 1-12 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651